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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/171,553	02/08/1999	DANIEL NORMAN GALBRAITH	CFV-005.01	8196

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EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
1632	AB

DATE MAILED: 12/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/171,553	GALBRAITH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ram R. Shukla	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 04 September 2002.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 43,46,48,49 and 51-65 is/are pending in the application.

4a) Of the above claim(s) 65 is/are withdrawn from consideration.

5) Claim(s) 48 is/are allowed.

6) Claim(s) 43,46,49 and 51-64 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)                            4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ .                    6) Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Applicant's response filed 9-04-02 has been received.
2. Claims 44, 45, 47 and 50 have been cancelled.
3. Claims 43, 48, 49, 56, 57 and 62 have been amended.
4. Claim 65 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 19.
5. This application contains claim 65 drawn to an invention nonelected with traverse in Paper No. 19. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
6. Claims 43, 46, 48, 49, 51-64 are under consideration.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
8. Claims 43, 46, 49 and 51-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record set forth in the previous office action of 3-28-02.

### ***Response to Arguments***

Applicant's arguments filed 9-04-02 have been fully considered but they are not persuasive. Applicants have argued that the specification clearly conveys to one skilled in the art that the applicants were in possession of the claimed genera,

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however they do not provide any evidence in support of their arguments. Different sections of the specification cited by the applicants do not address the issues of identifying characteristics of the species of the claimed genus and other issues. Applicants arguments that the specification teaches that these can be isolated by hybridization does not describe the structure of the claimed nucleic acid genus and hybridization may occur between nucleic acids sequences which may have sequence identity in shorter stretches. Therefore, the method of isolation cannot provide support for written description. Therefore, the written description requirement rejection is maintained for reasons of record.

9. Claims 43, 46, 49 and 51-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (i) an isolated polynucleotide disclosed in SEQ ID NO 1, 2 and 3 wherein the polynucleotides of SEQ ID NO 2 and 3 have three open reading frames (ORFs) of 524 (SEQ ID NO 4), 1194 (SEQ ID NO 5), and 656 amino acids each (SEQ ID NO 6) (ii) an isolated polynucleotide disclosed in SEQ ID NO 9 which encodes the protein disclosed in SEQ ID NO 10, vector comprising the polynucleotides of (i) and (ii), and an isolated recombinant host cell comprising the polynucleotides of (i) and (ii), does not reasonably provide enablement for any other claimed embodiments for reasons of record set forth in the office action of 3-28-02.

#### ***Response to Arguments***

Applicant's arguments filed 9-04-02 have been fully considered but they are not persuasive. Applicants' correction of the claim numbers is appreciated. Applicants have not addressed the specific questions raised in the previous office action. Applicants have only argued that the specification teaches how to isolated polynucleotides and that there are working examples and how to make nucleotides of 75% sequence identity. However, these arguments do not address the issues such as: whether the sequences disclosed in SEQ ID NO 1 is a smaller fragment of the polynucleotide disclosed in SEQ ID NO 3 or 2 whether it is an independent sequence; whether the polypeptides encoded by SEQ ID NO 1 and by 2 and 3 are same and/or how related they are; whether the polypeptides encoded by SEQ ID

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NO 1 ORF, 924 and 218 amino acids in length would have the activity of Env proteins encoded by SEQ ID NO 2 and 3. In the absence of any disclosure about the function of these polynucleotides it is not clear whether any of the fragments of SEQ ID NO 1 will encode any protein, which would have the physiological activity of the Pol, and Env protein. Regarding the polynucleotides that have at least 75% sequence identity, issues were raised as to which 25% of the nucleotide sequences disclosed could be changed without altering the activity of the encoded protein.

Accordingly, the specification is not enabling for the claimed invention because the specification does not provide sufficient guidance, working examples, and evidence as to how an artisan would have made and used the claimed invention without undue experimentation and therefore, limiting the scope of the claimed invention to (i) an isolated polynucleotide disclosed in SEQ ID NO 1, 2 and 3 wherein the polynucleotides of SEQ ID NO 2 and 3 have three open reading frames (ORFs) of 524 (SEQ ID NO 4), 1194 (SEQ ID NO 5), and 656 amino acids each (SEQ ID NO 6) (ii) an isolated polynucleotide disclosed in SEQ ID NO 9 which encodes the protein disclosed in SEQ ID NO 10, vector comprising the polynucleotides of (i) and (ii), and an isolated recombinant host cell comprising the polynucleotides of (i) and (ii), is proper.

### ***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

11. Claims 43-47 and 49-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Fishman (US 6190861, 2-20-2001, filing date 12-14-1995) for reasons of record set forth in the previous office action of 3-28-02.

***Response to Arguments***

Applicant's arguments filed 9-04-02 have been fully considered but they are not persuasive. It is noted that claim 43 b does not recite that the sequence has the recited identity over the entire sequence of the claimed sequence. Therefore, any parts of the sequence of Fishman et al that have sequence identity with parts of the claimed sequence will anticipate the claimed nucleic acid. Same will be true for claim 43 c and claim 49. Claim 46 recites that the polynucleotide of claim 43 encodes an envelope polypeptide and therefore, the cited art will meet the limitation. Regarding the oligonucleotides of claim 56, 57, 62 and 63 it is noted that fragments of the nucleic acid of Fishman will meet the limitations of these claims. Applicants table showing the comparison of the two sequences is not relevant since they compared the entire sequences, however the sequences as claimed are not limited to full length sequences of the SEQ Ids.

12. Claim 48 is free of the prior art of record and is allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

When amending claims, applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to **§ 1.121(c)**.

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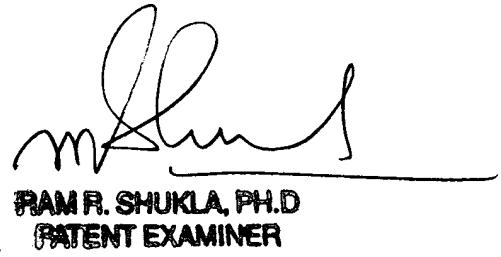
For instructions, Applicants are referred to

<http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm>.

Applicants are also requested to submit a copy of all the pending/under consideration claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Tiffany N. Tabb whose telephone number is (703) 605-1238.

Ram R. Shukla, Ph.D.



RAM R. SHUKLA, PH.D.  
PATENT EXAMINER